

PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Marlon D. Cowart, et al.

Serial No.: (not yet assigned)
(Divisional of 10/094,265 filed on March 8, 2002)

Filed: October 31, 2003

Title: BENZIMIDAZOLES THAT ARE
USEFUL IN TREATING SEXUAL
DYSFUNCTION

Case No.: 6789.US.D1

Examiner: (not yet assigned)

Group Art Unit: (not yet assigned)

EXPRESS MAIL NO.: EV314253307US

Certificate of Mailing under 37 CFR §1.10:

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Miriam Smith

INFORMATION DISCLOSURE STATEMENT

MS Patent Application
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Dear Sir:

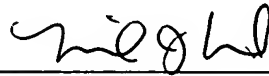
The following information is submitted, pursuant to 37 CFR §§1.97-1.98 in accordance with Applicant's duty of disclosure under 37 CFR §1.56. This submission is not intended to constitute an admission that any patent, publication or other information cited herein is "prior art" as to the invention claimed. In accordance with 37 CFR §§1.97(g)-(h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that other material information as defined by 37 CFR §1.56(a) exists.

Applicants submit herewith Forms PTO 1449 listing the references known to them. Applicants respectfully request that the Examiner (1) initial each reference listed on the enclosed Forms PTO 1449 indicating that the Examiner has considered and made those references of record in this application and (2) return a copy of the initialed Forms PTO 1449 to Applicants. Copies of references were previously submitted in U.S. Serial No. 10/094,265, filed March 8, 2002, from which this application claims priority.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits under 37 CFR §1.97(b). Accordingly, no charge is required.

Respectfully submitted,
Marlon D. Cowart, et al.

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Registration No. 37,960
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DATE: October 31, 2003

SHEET 1 of 4

Form PTO - 1449 (Modified)

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| FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (Modified) PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 CFR 1.98 (b)) | ATTY. DOCKET NO. 6789.US.D1 | SERIAL NO. |
| | APPLICANT(S) M. D. Cowart, et al. | |
| | FILING DATE October 31, 2003 | GROUP |

U.S. PATENT DOCUMENTS

| EXAMINER INITIAL | | PATENT NUMBER | ISSUE DATE | INVENTOR | CLASS | SUB CLASS | FILING DATE |
|---------------------|----|---------------|---------------|-------------------|-------|--------------|----------------|
| | A1 | 5,714,854 | 02/03/98 | Mizuta et al. | | | |
| | A2 | 5,792,768 | 08/11/98 | Kulagowski et al. | | | |
| | A3 | 3,472,854 | 10/14/69 | | | | |

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

| | | DOCUMENT NUMBER | PUBLIC- ATION DATE | COUNTRY OR PATENT OFFICE | CLASS | SUB CLASS | TRANS- LATION |
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| | | | | | | | YES NO |
| | | | | | | | |

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

| | | |
|--|-----|--|
| | C1 | Andersson, K. et al., "Physiology of penile erection," <i>Physiol. Rev.</i> 75:191-236 (1995) |
| | C2 | Bendele, A.M. et al., "Anti-Inflammatory Activity of Pergolide, a Dopamine Receptor Agonist," <i>Journal of Pharmacology and Experimental Therapeutics</i> 259(1):169-175 (1991) |
| | C3 | Berge, S.M. et al., <i>J. Pharmaceutical Sciences</i> 66:1et seq (1977) |
| | C4 | Chen, F.F. et al., "Effects of dopamine, Apomorphine, -Hydroxybutyric Acid, Haloperidol and Pimozide on Reflex Bradycardia in Rats," <i>Journal of Pharmacology and Experimental Therapeutics</i> 214(2):427-432 (1980) |
| | C5 | DeGroat, W. et al., "Neural Control of Penile Erection, in : Nervous control of urogenital system," <i>Hardwood Academic Publishers, Chur, Switzerland, Vol. 3 (ed. Maggi, C.):467-524 (1993)</i> |
| | C6 | Dula, E. et al., "Efficacy and safety of fixed-dose and dose-optimization regimens of sublingual apomorphine versus placebo in men with erectile dysfunction," <i>Urology</i> 56:130-135 (2000) |
| | C7 | Hahn, R.A. et al., "Primate Cardiovascular Responses Mediated by Dopamine Receptors: Effects of N, N-di-n-Propyldopamine and LY171555," <i>Journal of Pharmacology and Experimental therapeutics</i> 229(1):132-138 (1984) |
| | C8 | Harris, M. C. et al., "Sequential N-Arylation of Primary Amines as a Route to Alkyldiarylamines," <i>J. Org. Chem.</i> 64:6019-6022 (1999) |
| | C9 | Hrib, N. J., et al., "The dopamine D ₄ receptor: a controversial therapeutic target," <i>Drugs of the Future</i> 2000 25(6):587-611 |
| | C10 | Koch, V. et al., "Chemistry of 3-Hydroxypyridien part 2: Synthesis of 5,6-Dihalo-3hydroypyridines," <i>Synthesis</i> 499-501 (1990) |
| | C11 | Lissoni, et al., "Efficacy of bromocriptine in the treatment of metastatic breast cancer- and prostate cancer-related hyperprolactinemia," <i>Neuroendocrinology Letters</i> ISSN 21:405-408 (2000) |
| | C12 | Lynch, J.K. et al., "Efficient asymmetric synthesis of ABT-594; a potent, orally effective analgesic," <i>Tetrahedron: Asymmetry</i> 9:2791-2794 (1998) |
| | C13 | Melis, M et al., "Dopamine and Sexual Behavior," <i>Neuroscience and Biobehavioral Reviews</i> , 19(1):193-35 (1995) |

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|---------------------|---------------|---------------|------------------|-------|--------------|----------------|
| | 3,362,956 | 01/09/68 | | | | |
| | 5,714,498 | 02/03/98 | Kulagowski et al | | | |
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| 02/88093 | 07.11.02 | WO | | | |
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OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

| | |
|--|---|
| | Shvedov et al., "Catalytic alkylation of amines with alcohols," Zhurnal Organicheskoi Khimii 6(9):1838-1840 (1970) |
| | Pugsley et al., "The discovery of PD89211 and related compounds: selective dopamine D4 receptor antagonists," Progress in Neuro-Psychopharmacology & Biological Psychiatry 26(2):219-226 (2002) |
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| EXAMINER | DATE CONSIDERED |
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EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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| FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (Modified) PATENT AND TRADEMARK OFFICE | ATTY. DOCKET NO. 6789.US.D1 | SERIAL NO. (not yet assigned) |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | APPLICANT(S) M. D. Cowart, et al. | |
| (Use several sheets if necessary) | FILING DATE October 31, 2003 | GROUP (not yet assigned) |
| (37 CFR 1.98 (b)) | | |

| | |
|-----|--|
| C14 | Milligan, G. et al., "Chimaeric G proteins: their potential use in drug discovery," Trends Pharmacol Sci 20:118-124 (1998) |
| C15 | Missale, C. et al. "Dopamine receptors: from structure to function," Physiol Rev 78:189-225 (1998) |
| C16 | Morales, A. et al., "Oral and Topical Treatment of Erectile Dysfunction: present and future," Urologic Clinics of North America, vol. 22:879-886 (1995) |
| C17 | Moreland, RB, et al., "Prospectives for Pharmacotherapy of Male Erectile Dysfunction," Curr Opinion CPNS Invest Drugs, 2:283-302 (2000) |
| C18 | Padma-Nathan, H. et al., "Efficacy and safety of apomorphine SL vs. placebo for male erectile dysfunction," Urology 161:214 (abstract 821) (1999) |
| C19 | Primus, R. et al., "Localization and characterization of dopamine D ₄ binding sites in rat and human brain by use of the novel D ₄ receptor-selective ligand [³ H]NGD 94-1," J. Pharmacol Exp. Ther 282:1020-1027 (1997) |
| C20 | Sule, D.P. et al., "Synthesis and Anthelmintic activity of 2-(N4-Substituted-N1-Piperazinyl) Methyl 5-(or 6) - substituted benzimidazoles," Bull. Haffkine Inst. 6(2):62-64 (1978) |
| C21 | Suzuki, M. et al., "D ₃ dopamine receptor mRNA is widely express in human brain," Brian Res 779:58-74 (1998) |
| C22 | Vallone, D. et al., "Structure and function of dopamine receptors," Neurosci Biobehav. Rev. 24:125-132 (2000) |
| C23 | Wagaw, S. et al., "The Synthesis of Aminopyridines: A Method Employing Palladium-Catalyzed Carbon-Nitrogen Bond Formation," J. Org. Chem 61:7240-7241 (1996) |
| C24 | Yang B. et al., "Palladium-catalyzed amination of aryl halides and sulfonates," Journal of Organometallic Chemistry 576:125-146 (1999) |
| C25 | "IUPAC 1974 Recommendation for Section E, Fundamental Stereochemistry," Pure Appl. Chem. 45:13-30 (1976) |
| | |
| | |

EXAMINER

DATE CONSIDERED

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|--------------------|----------------------|-----------------------------|-------|--------------|----------------------------|
| 98/31368 | 23.07.98 | WO | | | |
| 00/23056 | 27.04.00 | WO | | | |
| 0 882 718 | 09.12.98 | EP | | | |
| 0 468 884 | 24.07.91 | EP | | | X |
| 2 154 605 | 14.09.99 | ES | | | X |

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

| | |
|--|---|
| | Bivalacqua et al., "Pharmacotherapy for erectile dysfunction," TIPS 21:484-489 (2000) |
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